Pharmacy NewsCapsule

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Regulation Interpretation

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Pick up any set of regulations and turn to the pharmacy section. Many of the pharmacy regulations are specific. For example, "all medications must be locked." Taken at face value the rule means all medications in the facility must be locked.

However, regulations on resident rights, and resident or patient treatment plans may conflict with the locked medications regulation. For example, regulations for individual treatment plans may require or allow patients to self-administer their medications once they are taught to do so. As part of this treatment plan, medications may be stored and/or packaged differently and therefore not locked. Would this be a violation?

Technically, having unlocked medications in the facility is a violation. However, not teaching medication administration and allowing the patient or resident to self-administer would be another violation. The point is all regulations must be kept in context and a decision must be made based on the current situation and treatment plan. The important aspect to keep in mind is that the patient or resident is getting the best care in the safest environment. Best care may mean keeping medications unlocked in a place that promotes safety and independence. In this case unlocked medications would not be a violation as it promotes patients' rights to self-administer the medication.

Inside This Issue

Antidepressants: Are they a "good thing?"

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No, Martha Stewart did not write this feature.

Psychotropic drug use has been on the increase in Wisconsin elderly for the last few years. Much of this increase can be attributed to the increased recognition of depression and subsequent treatment of it with antidepressants. Treatment for depression is a good thing. Unfortunately there are some negative consequences that may be occurring.

A very harmful result is overlooked medication side effects. Let's take a look at the problem. Many new antidepressant medications have been approved in recent years. These medications have worked extremely well and have fewer side effects. They are promoted and accepted as very safe medications. However, when medications are considered completely safe the use and monitoring often becomes relaxed. In the elderly this is a recipe for disaster.

Antidepressants like Prozac®, Zoloft®, and Remeron® do have side effects and the effects tend to be more pronounced in elderly individuals. Also, elderly individuals tend to be on additional medications that interact with antidepressants thereby increasing adverse events. So when evaluating changes in behavior, constipation, falls and other significant changes, the side effects of antidepressants should not be overlooked.

Another consideration is psychotropic medications, like many other medications, are often started for a single incident and then continued for many years. For example, an isolated case of sadness or crying may result in the use of an antidepressant that is continued indefinitely. Another example is the use of a medication for one night of sleeplessness that leads to the use on a continuous basis. Yet another example could be the continuos use of digoxin for "a heart condition" diagnosed ten years ago.

Cont. page 3

New Drugs

Doug Englebert *Pharmacy Practice Consultant PRQI*

This month's new drug list reviews all of the new medications approved in 2001.

Brand Name	Generic Name	Use
Arixtra	Fondapariunx	Injection for deep vein thrombosis
Axert	Almotriptan	Tablet for migraine headaches
Bextra	Valdecoxib	For arthritis
Cancidas	Caspofungin	Unresponsive aspergillosis
Clarinex	Desloratidine	Tablet for allergic rhinitis
Definity	Perflutren	Used in echocardiography
Dutasteride	Dutasteride	Capsule for benign prostatic hyperplasia
Elidel	Pimecrolimus	Used for ezcema
Foradil	Formoterol fumarate	Asthma or bronchospasm treatment
Frova	Frovatriptan	Tablet for migraine headaches
Geodon	Ziprasidone	Antipsychotic
Gleevec	Imatinib mesylate	Chronic myeloid leukemia
Invanz	Ertrapenem	Antibiotic
Kineret	Anakinra	Inj for Rheumatoid Arthritis
Lumigan	Bimatropost	Eye drop for glaucoma
Natrecor	Nesiritide	Acute congestive failure
Nuvaring	Etonogestrel	Vaginal contraceptive ring
Ortho Evra	Norelgestromin	Contraceptive patch
Reminyl	Galantamine	Alzheimer's
Spectracef	Cefditoren pivoxil	Tablet antibiotic
Tracleer	Bosentan	Tablet for pulmonary hypertension
Travatan	Travopost	For glaucoma
Viread	Tenofovine	Tablet for HIV
Xigris	Drotrecogin alfa	Severe sepsis with acute organ failure
Yasmin 28	Drosperinone	Oral contraceptive
Zometa	Zoledronic Acid	Hypercalcemia of malignancy

Med Error Corner

Doug Englebert Pharmacy Practice Consultant

A short comment for thought related to reporting medication errors:

Learning comes with genuine openness.

Focus Drug of the Month

Doug Englebert
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Clozaril®, clozapine

Clozaril® (clozapine) is an atypical antipsychotic used for individuals with schizophrenia that do not respond to another antipsychotic. It is currently not recommended by the manufacturer labeling it to be used for non-psychotic symptoms associated with dementia or other diseases in elderly.

This medication has been considered a wonder drug for many individuals with schizophrenia that had no other alternatives in the past.

Clozaril® is heavily controlled and monitored due to a severe side effect called agranulocytosis, which can be life threatening. Specifically, individuals on this medication are placed on a clozapine registry and have blood drawn weekly to check white blood cells. If white blood cell counts drop too low, the medication is stopped.

These requirements have been in place for a while and most individuals who work with this drug are well versed in the process and concerns of the side effects.

Recently, the manufacturers of Clozaril®, in coordination with the Food and Drug Administration (FDA), have issued a new 'black box warning.' The warning states that there have been 30 deaths reported in patients who were on clozapine and developed myocarditis.

It goes on to note that anyone on clozapine that develops unexplained fatigue, dyspnea, fever, chest pain, palpatations, tachypnea or other

Continued on page 3

Antidepressants --Continued from page 1

To avoid negative consequences, single incidences need to be fully evaluated. Sometimes it may seem easier to start a medication and continue it if there is a positive response. However, is the positive response due to the medication or because the issue is a single behavior or incidence? Treating single incidence in the elderly tends to lead to situations of duplicate therapy, drug-drug interactions, and other adverse effects.

Here is an example. An individual has a single seizure and is started on phenytoin. Since it is a single seizure, of course the medication works and the treatment plan continues the phenytoin. In fact the medication is continued for ten years with no seizure reoccurring. Unfortunately, the individual develops another condition requiring additional medications. These medications interact with phenytoin leading to phenytoin toxicity. This interaction could have been prevented with complete assessment of the single incident or by reevaluating and trying to take the individual off the phenytoin to see the results.

As surveyors, how can you impact this phenomenon? When there is a concern with adverse effects and you are looking at medication regimen, concentrate on new medications started recently. Why was it started? Was it a single incidence? Was the incidence completely evaluated? Are there adverse effects occurring?

Fixing something that is not broken is against human nature; when it comes to medications, eliminating those that appear to be working, but may not be necessary because it was started for a single incidence, avoids a potential negative outcome.

The drug regimen review guide that you are provided lists information on side effects including all of the antidepressants. Review the guide when considering medications on survey. Focus on the newly started medications and changes that have recently occurred. Ask the facility, contact the consultant pharmacist or consult the prescribing physician to discuss concerns you may be having. Contact me if there are any questions.

Capsule Quiz

(The first surveyor to answer the following question by sending me an E-mail with the correct answer will win a bag of M&Ms.)

What is valdecoxib and what are the side effects that should be monitored?

Thank you to those who have responded to the survey. The response rate has been about 5% so I am looking for additional responses. E-mail surveys to engleda@dhfs.state.wi.us or fax to 608-267-7119. If you need a copy let me know. I appreciate the time you take to fill out this survey.

symptoms of heart failure should be evaluated for mycoarditis. Tachycardia, which has been associated with clozapine, has also been identified as a presenting symptom of myocarditis. Therefore, tachycardia in the first month of clozapine should be evaluated for myocarditis.

If myocarditis is suspected, prompt discontinuation of clozapine is warranted. Patients that have developed clozapine induced myocarditis should not be re-challenged with clozapine.

Clozapine has been a life saving medication for many people. This new warning is significant and requires additional monitoring; however, it should not deter the use for those patients that require it and respond favorably without the side effects.

Antipsychotics

Antipsychotics and diabetes??? There are increasing reports of Type II diabetes developing from use of an atypical antipsychotic (Risperdal®, Seroquel®, Zyprexa®). How should this risk be managed?

1) Risks of diabetes should be considered before the antipsychotic is used.

2) Individuals that are at risk should have monitoring or screening for diabetes, which may include a baseline and follow-up plasma glucose.

Hyperglycemia can increase morbidity for patients and should not be dismissed.

If there are medications you would like featured here please send an e-mail to Doug at engleda@dhfs.state.wi.us

Consultant's Corner

Doug Englebert *Pharmacy Practice Consultant PRQI*

This section is basically a miscellaneous section that will show up each issue and will contain tidbits of information, most of which will come directly from your questions. If there is a topic you want more detailed information about, please drop me an e-mail at engleda@dhfs.state.wi.us and I'll see what I can find.

1) What is the requirement for pharmacist drug review and reporting in a nursing home?

Nursing home regulations require a pharmacist to complete a drug regimen review for drug irregularities or potential irregularities. Any irregularities the pharmacist identifies must be reported to the attending physician and director of nursing.

The state operations manual Appendix PP and Appendix N list many target medications and irregularities that pharmacists should be reviewing. These irregularities are just a start. Obviously there are many other medications, drug interactions and adverse effects that pharmacists may identify.

Very often questions arise on how soon irregularities should be communicated. Typically, communication to the attending physician and director of nursing depends on the situation. Critical irregularities should be reported and acted upon immediately. Physicians may not act upon non-critical irregularities until the next resident visit.

Sometimes when pharmacists are completing their drug review, they may not have all the information that is needed to determine if they have a drug irregularity. Therefore sometimes, as a surveyor, you may see a pharmacist report that asks for information to determine if there is an irregularity. Very often these requests may only go to the director of nursing. These types of requests for information reports may not and do not need to be reported to the attending physician. Another issue to consider is that reporting and timing of the report to the director of nursing may be different than to the attending physician. For example, some irregularities that have not resulted in problems, e.g., drug storage, may be more important to immediately inform the director of nursing but informing the attending physician can wait until the next visit.

2) We have a resident/patient who is self-administering medications and stores their medications at bedside in a locked drawer. Can he also store his narcotics in this locked drawer as well?

Various facility regulations, nursing homes, community based residential facilities and others have policies and procedures regarding storage of medications. Typically the regulations also have a separate requirement for controlled substances that are considered Scheduled II. Very often the Schedule II requirement is to have these medications "double locked." This means that the medication is in a locked container and stored in another locked room.

Back to the question. In most cases those individuals who self-administer can store medications at bedside. In most cases they must only be secured which does not mean they must be locked. The same would be true for Schedule II controlled substances. However, typically the regulations concerning self-administration require a physician's order and physician or team evaluation for the patient or resident to do so. Typically, the regulations require the evaluation to include guidelines as to how the resident or patient should store their medications.

The last consideration that a facility should take in relation to residents or patients storing their own medications is the safety of other residents or patients. The medications need to be stored to promote the use by the self-administering patient or resident and to protect the inadvertent use by other residents and patients.

3) Is baby aspirin EC equivalent to regular baby aspirin?

Enteric coated (EC) baby aspirin is not equivalent to regular baby aspirin. Very often physicians may write an order for over the counter EC baby aspirin. For many reasons including expense, pharmacies may decide to supply the facility with over the counter <u>regular</u> baby aspirin. Facilities should confirm the physician order and assure that the over the counter medication supplied matches the physician order.

References are available upon request.